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The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Vitamin E acts as an inhibitor of oxidation processes in body tissues. It protects unsaturated fats in the body from oxidation by peroxides and other free radicals.*
- (2) Vitamin E is especially active in tissue cell walls, where it protects lipid membranes and strengthens this most basic cellular defensive line. It is also essential to the proper function of lysosomes, tiny organelles within the cell, transporters of potent chemicals that help maintain cellular security.*
- (3) The vitamin E and soy bean oil extract in Wheat Germ Oil Perles Fortified support the cell membranes of all tissue in the human body, especially those in the nervous system. Vitamin E is an anti-oxidant that protects and repair cell membranes, especially those of nerve cells, from damage by the highly reactive oxygen compounds known as free radicals.*
- (4) The vitamin E and soy bean oil extract in Wheat Germ Oil Perles Fortified support the proper functioning of the cardiovascular system. Vitamin E in wheat germ oil protects lipoproteins in the blood from damage by free radical oxygen and in doing so helps prevent the buildup of fatty deposits in the cell wall of the cardiovascular system.*
- (5) The vitamin E and soy bean oil extract in Wheat Germ Oil Perles Fortified maintains eye lens transparency.*
- (6) The vitamin E and soy bean oil extract in Wheat Germ Oil Perles Fortified protects material in the cell nucleus from damaging free radicals. It also detoxifies singlet oxygen and peroxy radicals, thus protecting cell membranes, including those adjacent to nucleic material.*

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These statements are made for a dietary supplement containing wheat germ oil and soy bean oil extract. The name of the product is Wheat Germ Oil Perles Fortified™.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

